

### **REMARKS**

The present paper is responsive to the final Office Action mailed on August 16, 2010. By this paper, the Applicants request reconsideration of the rejections.

Claims 33 and 66-68 are amended to recite a pH-sensitive mucoadhesive layer, and to recite that that layer comprises a water insoluble swellable anionic mucoadhesive polymer and an anionic pH-sensitive film-forming copolymer of methacrylic acid and acrylic or methacrylic ester. Claim 66 is further amended to recite that the pH-sensitive mucoadhesive layer comprises a water insoluble swellable anionic mucoadhesive polymer of polyacrylic acid cross-linked with polyalkenyl ether or divinyl glycol. No new matter is added, since those limitations are imported from now-canceled dependent claims. Support for the term anionic is set forth below again in item A.

#### **A. THE REJECTION OF CLAIMS UNDER 35 U.S.C. §112 IS BELIEVED TO BE OVERCOME.**

##### **1. The rejection of claims over the term “anionic.”**

The Examiner rejects claims 33-34, 36-46, 51, 56-57, and 63-68 as failing to comply with the written description requirement. It is believed that the foregoing amendments, specifying a pH-sensitive mucoadhesive layer including anionic mucoadhesive polymers of polyacrylic acid cross-linked with polyalkenyl ether or divinyl glycol and anionic pH-sensitive film-forming copolymers of methacrylic acid and acrylic or methacrylic ester, overcome the rejection. The specification both conveys the concept and provides specific examples of the claimed subject matter, satisfying any requirement imposed by Section 112.<sup>1</sup> See at least *page 16, ll 19-23*, reciting “Examples of pH-sensitive film-forming polymers that meet these criteria are, but not limited to, Eudragits® and cellulose acetate phthalate polymers, or derivatives thereof. Eudragits® are synthetic cationic and anionic polymers of methacrylic acid and methacrylic acid esters in varying ratios” (emphasis added). Thus, support is found in the present specification for both cationic and anionic pH-sensitive film-forming Eudragit® polymers. See also the specification at *page 17*, first partial paragraph (especially *ll 15-17*), reciting: “No references or other prior art could be found that describe the use of mucoadhesive gels comprised of anionic polymers ...” Finally, see at least *Figure 2*,

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<sup>1</sup> *In re Anderson*, 471 F.2d 1237, 176 USPQ 331(CCPA1973).

Figure 3, and Figure 6 showing results from wax-film composites comprising Eudragit® S100, and also at least Examples 7 and 8 describing the making of a wax-film composite comprising Eudragit® S100, and also Examples 1, 2, 5, and 6 describing the making of a pH-sensitive mucoadhesive film-forming gel comprising Eudragit® L100. As demonstrated to the Examiner in a previous response (see **Exhibit B** appended to the response filed on July 15, 2010), these are well-known to be anionic copolymers of methacrylic acid and acrylic or methacrylic ester. It is believed that the amendments satisfy any requirement of §112, 1<sup>st</sup> paragraph, and withdrawal of the rejection of the claims as failing the written description requirement is respectfully requested.

**2. The rejection of claims for the limitations “consisting essentially of” and “consisting of.”**

The Examiner rejects claims 3-34, 36-46, 51, 56-57, 63-65 and 68 for inclusion of the above transitional phrases. The basis for this rejection is not understood. While not a *per se* rule, the Board of Patent Appeals and Interferences has found that the case law supports a narrowing amendment of claims from “comprising” to “consisting essentially of” in certain situations.<sup>2</sup> The Board has also expressly stated that the question of proper written description support is a question of fact,<sup>3</sup> and in *Ex parte Daniel Charquet* further found that the same narrowing amendment was supported because the Applicants were clearly in possession of the claimed subject matter. Such is the case here. The Examiner’s attention is directed at least to Figure 1, showing a composite of a pH-sensitive mucoadhesive layer and a water-insoluble wax layer with water swellable polymer, and also to the specification, at least at Examples 7-9 describing preparation of composites consisting of Noveon®, Eudragit S100®, and Dentsply® utility wax and Examples 10-12 describing preparation of composites consisting of Noveon®, Eudragit S100®, and Dentsply® utility wax and a molecule of interest (plasmid DNA, hirudin, and hirudin/chitosan, respectively). The Applicants were clearly in possession of the

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<sup>2</sup> *Id.*, citing *Norian Corp. v. Stryker Corp.*, 432 F.3d 1356, 1360 (Fed. Cir. 2005) (during prosecution claim narrowed by changing the transitional phrase in the preamble from “comprising” to “consisting essentially of”).

<sup>3</sup> *Ex parte Daniel Charquet*, Jean-Paul Mardon and Jean Senevat, Appeal 2009-005023, Sept. 25, 2009 (BPAI 2009).

claimed subject matter, satisfying any requirement of Section 112. Reconsideration is respectfully requested.

**3. The rejection of claims 37-38, 40-41, 42-43, 45, and 63 for inclusion of trademarks/trade names.**

It is believed that the foregoing amendments address the Examiners concerns regarding the listed claims. The rejection of claim 42 is not understood, since that claim includes no trademarks/trade names. Likewise, the rejection of claim 45 for the term “tragacanth” is not understood, since that is not a trademark/trade name. Rather, the term refers to a natural gum obtained from several species of Middle Eastern legume.<sup>4</sup> Reconsideration is requested.

**4. The rejection of claim 63 for the limitation “from about 2:1 to about 4:1.”**

It is unclear to the Applicant whether the Examiner withdrew the prior rejection of claim 63 as failing the written description requirement for the limitation concerning Noveon:Eudragit ratios between about 2:1 to about 4:1, since that rejection was not specifically mentioned but the Action states that the claims, including claim 63, are rejected as failing to comply with the written description requirement “for the reasons set forth in the previous office action.” In the previous response filed on July 15, 2010, the Applicant amended the claim to recite a limitation of “between 2:1 to 4:1.” To ensure a complete response and record, the Applicant again points out that the “... analysis must take into account which ranges one skilled in the art would consider inherently supported by the discussion in the original disclosure.”<sup>5</sup> In the present case, ranges are expressly disclosed in the Specification which are not so far-reaching as to cause the skilled artisan to question whether the intervening ratios were contemplated. This is not the case where upper, middle, and lower limits are disclosed which represent such a gap as to allow for near-infinite intervening possibilities, whereby claiming the range between the upper and lower ratios violates the written description requirement. That is, the skilled artisan, presented with the specific examples of ratios of 2:1, 3:1, and 4:1 of two compositions, would consider a ratio range of from 2:1 to 4:1 to have been described at least inherently,

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<sup>4</sup> See <http://en.wikipedia.org/wiki/Tragacanth>.

<sup>5</sup> MPEP §2163.05, at pg. 2100-190.

if not expressly. Following the logic of *In re Wertheim*<sup>6</sup>, it is believed that Section 112 does not require the Applicant to provide specific examples of the fractional increments between the presently discussed ratios, since the upper, lower, and middle ratios are expressly disclosed. The Office has not met its burden of providing reasons why a description not in *ipsis verbis* is insufficient, and therefore this portion of the rejection is believed to have been rebutted. The rejection should be withdrawn.

**B. THE REJECTION OF CLAIMS 33-34, 36-37, 42-46, 56-57, 65, AND 67 UNDER 35 U.S.C. §103(A) OVER SLAVTCHEFF AND SUZUKI IS BELIEVED TO BE OVERCOME.**

The Examiner maintains the position that the above claims are obvious over the teachings of Slavtcheff in view of Suzuki, with Suzuki being cited solely for teachings of thin layers for adhesive patches and for use of a wax backing layer. It is believed that the foregoing amendments and the arguments that follow overcome this rejection, in that no combination of the references articulates any teaching or reason to consider the anionic polymers as recited in the amended claims to provide a pH-sensitive mucoadhesive layer for delivering a molecule of interest to a mucosal area, that layer including both a water-insoluble swellable anionic mucoadhesive polymer and an anionic pH-sensitive film-forming polymer as claimed. The *prima facie* case for obviousness is insufficiently supported, and the rejection should be withdrawn.

Again, Slavtcheff teaches adhesive cosmetic strips (see *Abstract*) including a flexible water soluble substrate, an adhesive composition deposited onto the substrate, a liquid crystal thermochromic substance, and an agent interactive with water to ensure a specified temperature rise. Only adherence to derma is contemplated. That is, nowhere does Slavtcheff teach or hint at use of a *mucoadhesive* layer, much less the synthetic anionic mucoadhesive polymer expressly claimed herein. Rather, Slavtcheff exclusively contemplates adhesives for securing its color-changing cosmetic strip (see *Col. 1, ll 61-63*) to skin surfaces (*Col. 3, ll 1-4*). This is needed for a primary function of the dermal strip of Slavtcheff, that is, for the adhesive to dry over the area of treatment whereby keratotic plugs adhere to it (*Col. 5, ll 18-24*). Thus, it cannot fairly be said that Slavtcheff articulates any reason for the skilled artisan to consider a pH-sensitive anionic

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<sup>6</sup> *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976).

mucoadhesive polymer, much less the precisely claimed polymer of the present independent claims.

Not only does Slavtcheff lack any hint of a mucoadhesive layer, Slavtcheff provides no teaching, nor is there any indication that Slavtcheff at all contemplates, a synthetic *pH-sensitive* anionic mucoadhesive layer for delivery of a molecule of interest to mucosa as a function of pH as is expressly claimed herein. Rather, Slavtcheff recites only a temperature-sensitive dermo-adhesive layer comprising liquid crystal thermochromic substances (*Col. 2, ll 25-65*) wherein a water-interactive agent induces a temperature change of at least 2 ° C (*Col. 2, ll 15-17*) which causes the thermochromic substances to change color to provide a visual indicator to the consumer that the dermal strip has been in place for a sufficient period of time. There is simply no indication in Slavtcheff of any need or reason for pH-sensitivity. This is to be expected since the Slavtcheff strip is only intended for removing keratotic plugs from skin pores, rather than for delivering molecules to mucosal areas.

The Examiner's rejection appears to be based solely on the Slavtcheff recitation of various ingredients, including monomers such as methacrylic acid (*Col. 4, ll 51-54*), Carbomer® (*Col. 5, ll 15-17*), and others (see *Col. 5* and *Col. 6*), for use in its dermal adhesives, rather than any reason articulated provided by Slavtcheff/Suzuki or the knowledge in the art to consider combinations resulting in the particular pH-sensitive mucoadhesive polymers of the present disclosure. Indeed, in rebutting the Applicant's prior arguments, the Examiner further states (in reference to the trademark Carbomer®) that "[T]he same compound is the same no matter what the name is given to the compound." Again, however, it is believed that particularly in the chemical arts, mixing of even the same ingredients, in different proportions and/or under different conditions, can lead to compositions having very different and unexpected properties. Further, as stated by the Examiner himself, "the trademark or trade name cannot be used properly to identify any particular material or product" (see page 3 of the most recent Action). For that reason, it is believed that even if it is accepted that Slavtcheff/Suzuki teach or suggest every element of the present independent claims (which as set forth above they do not), the references do not provide the requisite expectation of success that is a necessary underpinning of any finding of obviousness.

In this regard, the Examiner points to no element of Slavtcheff/Suzuki teaching or even hinting at an adhesive having mucoadhesive properties as expressly claimed herein, and certainly Slavtcheff/Suzuki provides no teaching or reason to consider a *pH-sensitive* anionic mucoadhesive polymer for delivering a molecule to mucosa. Rather, at most Slavtcheff/Suzuki provide motivation to consider combinations for adhering only to skin, with no motive for the skilled artisan to consider any issue of or requirement for pH sensitivity or mucoadherence. Even further, there is no indication in Slavtcheff/Suzuki leading the skilled artisan to consider the combination of a water-insoluble swellable anionic mucoadhesive polymer and an anionic pH-sensitive film-forming polymer as presently claimed to provide such a pH-sensitive anionic mucoadhesive polymer for delivering a molecule to mucosa.

Rather, Slavtcheff is exclusively directed to an adhesive for adhering to skin, not mucosa, for the recited purpose of removing keratotic plugs, and contemplates only a thermochromic property. Suzuki teaches only a wax backing layer. There is simply no hint or reasoning provided by the references leading the skilled artisan to even consider any issue of pH sensitivity in the resulting compositions. Thus, absent undue experimentation or use of the present Applicant's specification as a blueprint, each of which is improper, no guidance (or articulated reason) is given to the skilled artisan to arrive at or even consider using any of the Slavtcheff/Suzuki teachings to formulate the presently claimed combination of at least one water-insoluble swellable anionic mucoadhesive polymer and at least one anionic pH-sensitive mucoadhesive polymer for delivering a molecule of interest. The Examiner cannot ignore the present claim limitations of pH-sensitivity and mucoadhesiveness for convenience in making a rejection, and the mere recitation of related compositions do not provide any teaching or guidance leading the skilled artisan to consider those limitations. As such, Slavtcheff/Suzuki, for lack of any teaching or articulated reason for considering this claim limitation, does not teach or suggest each and every claim limitation, and therefore fails to establish the *prima facie* case for obviousness.

Still more, even post-KSR it remains a requirement that the skilled artisan be provided some reason for arriving at each and every claim limitation, and further it remains a requirement that the skilled artisan be provided some reasonable expectation of

success of combining the prior art teachings to arrive at each and every claim limitation. Merely pointing to the presence of claim elements in the prior art does not suffice as a complete statement of a rejection for obviousness.<sup>7</sup> Rather, a rejection of claims based on the rationale that the claimed invention is a combination of prior art elements also requires a finding that the results flowing from the combination would have been predictable to the skilled artisan.<sup>8</sup>

Admittedly, under the current guidelines on obviousness analyses an “obvious to try” rationale, that is, combining selected elements from one or more prior art references, can support a rejection under 35 U.S.C. §103 under certain circumstances.<sup>9</sup> However, even under *KSR* and post-*KSR* case law, this only applies when there are a “finite number of identified, *predictable* solutions, with a *reasonable expectation of success*” (emphasis added), and the *KSR* requirement for providing an objective reason leading the skilled artisan to combine references remains. That is, the reasonable expectation of success

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<sup>7</sup> Examination Guidelines Update: Developments in the Obviousness Inquiry after *KSR* v. Teleflex, Fed. Reg. Vol. 75, No. 169, Sept. 1, 2010, citing *Crocs, Inc. v International Trade Commission*, 598 F.3d 1294 (Fed. Cir. 2010).

<sup>8</sup> *Id.*, see also Manual of Patent Examining Procedure §2143 A(3). To reject a claim as *prima facie* obvious based on features disclosed in one or more references, there must be some suggestion, either in the art itself or in the knowledge available to the skilled artisan, of the desirability of making the combination (Manual of Patent Examining Procedure ch. 2100, Section 2143.01, p. 131: “The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.”) (Emphasis in original). Still further, it is required that a reasonable expectation of success support the finding of obviousness. *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986). Thus, the *prima facie* case of obviousness is established only when the teachings from the prior art, the knowledge available to the skilled artisan, or a combination thereof would appear to have suggested the claimed subject matter to a person of ordinary skill in the art. *In re Bell*, 991 F.2d 781, 783, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993). Also, despite any recent revisions to the MPEP, it remains a requirement to a finding of obviousness that the prior art reference or references must teach or suggest all the claim limitations. Manual of Patent Examining Procedure §2143. This test for *prima facie* obviousness is consistent with the legal principles set forth in *KSR Int'l Co. v. Teleflex Inc.* (127 S.Ct. 1727 (2007), 82 USPQ2d 1385 (2007). Summarizing the Supreme Court’s holding in that case, the Federal Circuit Court of Appeals noted that “... the Court acknowledged the importance of identifying ‘a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does’ in an obviousness determination.” *Takeda Chemical Industries Ltd. v. Alphapharm Pty.*, 83 USPQ2d 1169 (Fed. Cir. 2007) (quoting *KSR*, 127 S. Ct. at 1731). When determining whether a claim is obvious, an Examiner must make “a searching comparison of the claimed invention - including *all its limitations* - with the teaching of the prior art.” *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995). Moreover, “there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006).

<sup>9</sup> See, Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*, Fed. Reg. 72, No. 195, 57526-57535, at pg. 57529.

requirement remains, even when the particular facts permit an “obvious to try” analysis for legal obviousness.<sup>10</sup>

In the present case, however, the skilled artisan is not faced with a “finite number of identified, *predictable* solutions, with a *reasonable expectation of success*” of a pH-sensitive mucoadhesive layer comprising a water-insoluble swellable anionic mucoadhesive polymer and an anionic pH-sensitive film-forming copolymer of methacrylic acid and acrylic or methacrylic ester as claimed herein, leading to a *prima facie* case of obviousness. Rather, the skilled artisan is provided only a lengthy list of ingredients, with no reason articulated for the skilled artisan to consider any particular combination thereof to arrive at the presently claimed subject matter other than the guidance provided by the present specification. As discussed above, Slavtcheff/Suzuki fails to teach or provide the skilled artisan an articulated reason to consider a pH-sensitive mucoadhesive layer including at least one water-insoluble swellable anionic mucoadhesive polymer and at least one anionic pH-sensitive film forming polymer as expressly claimed herein. Therefore, neither Slavtcheff, Suzuki, nor any reasonable combination thereof teach or suggest each and every limitation of the present independent claims, nor is any reason articulated that would lead the skilled artisan to use the references independently or in combination to arrive at the presently claimed subject matter. The *prima facie* case of obviousness is not properly supported as to the independent claims, and the rejection must fall. Likewise, the claims depending from claim 33 are in condition for allowance without consideration of obviousness.<sup>11</sup> Reconsideration of the rejection over Slavtcheff and Suzuki is respectfully requested.

**C. THE REJECTION OF CLAIMS 33-34, 36-46, 51, 56, 57, AND 63-68 UNDER 35 U.S.C. §103(A) OVER SLAVTCHEFF/SUZUKI, FURTHER IN VIEW OF MANTELLE.**

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<sup>10</sup> *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc.*, (2007-1223 (Fed. Cir. 2008) (“... the passage in KSR posits a situation with a finite, and in the context of the art, small or easily traversed, number of options that would convince an ordinarily skilled artisan of obviousness.”); see also *Takeda Chemical Industries Ltd. v. Alphapharm Pty.*, 83 USPQ2d 1169 (Fed. Cir. 2007).

<sup>11</sup> *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992) (“[D]ependent claims are nonobvious if the independent claims from which they depend are nonobvious”); *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).



The Examiner takes the position that the above claims are obvious over the teachings of Slavtcheff in view of Suzuki, further in view of Mantelle. Slavtcheff and Suzuki are cited for the propositions addressed above. Mantelle is cited for a teaching of “use of Noveon® and Eudragit® polymers in adhesive compositions for personal use.”

It is believed that the foregoing amendments and the discussion above of the failure of Slavtcheff/Suzuki to support a *prima facie* case for obviousness likewise rebuts this rejection, the citation to Mantelle for the known trade names/trademarks Noveon® and Eudragit® notwithstanding. For the reasons set forth above, Slavtcheff/Suzuki fail to teach or articulate a reason for the skilled artisan to include a pH-sensitive mucoadhesive layer as expressly claimed herein for delivery of a molecule of interest to a mucosal surface, comprising at least one water-insoluble swellable anionic mucoadhesive polymer and at least one anionic pH-sensitive film forming polymer, or to provide the requisite expectation of success. Likewise, inclusion of Mantelle’s recitation of the known product line of Noveon® and Eudragit® polymers to the analysis does not adequately support the *prima facie* case for obviousness.

The lengthy teaching of ingredients set forth at least in Slavtcheff and Mantelle does not, without more, provide a basis for an obviousness rejection despite any recent revisions to the Manual of Patent Examining Procedure. As stated above, some articulated reason for combining those teachings with a reasonable expectation of success of arriving at the presently claimed subject matter is needed, independent of the mere recitation of ingredients in the prior art and the blueprint provided by the present Applicant’s specification. The trade names Noveon® and Eudragit® are applied to a range of different polymers having a range of properties, and thus Mantelle’s (and the Examiner’s) mere recitation of the trade names does not and cannot rise to the level of a teaching or articulated reason sufficient to provide the skilled artisan a reason to consider combining the teachings of Slavtcheff, Suzuki, and Mantelle to arrive at a pH-sensitive mucoadhesive layer as precisely set forth in the amended independent claims.

For that matter, in the latest Action the Examiner has rejected claims of the present application as uncertain in scope for including trade names/trademarks, arguing that “... the trademark or trade name cannot be used properly to identify any particular material or product.” In view of the wide range of compositions branded under the

names Noveon® and Eudragit® (and the wide range of properties thereof), surely the same logic applies in turn to the Section 103 rejection, in that the requisite articulated reason is lacking for selecting particular compositions to arrive at the claimed pH-sensitive mucoadhesive layer comprising a water-insoluble swellable anionic mucoadhesive polymer and an anionic pH-sensitive film-forming polymer as presently claimed. Stated differently, the combination of Slavtcheff/Suzuki/Mantelle provide no reason leading the skilled artisan to arrive at the present combination as claimed, the Mantelle recitation of Noveon® and Eudragit® notwithstanding, and likewise offer no reasonable expectation of success. At most, what is provided is an invitation to experiment.

Also, Mantelle expressly leads the skilled artisan towards a combination of PVP and another bioadhesive (*Col. 4, ll 65 et seq.*: "... the inventors believe that the combination of PVP and another bioadhesive provides for a superior adhesion not attainable by either the PVP or another bioadhesive alone."), unlike the present disclosure and claims. As set forth in a previous response, PVP is a neutral polymer. Thus, Mantelle would not motivate the skilled artisan to consider adhesive polymers without PVP, but rather guides the skilled artisan to inclusion of the neutral polymer. In contrast, the present independent claims 67 and 68 require that the claimed anionic pH-sensitive mucoadhesive polymer include at least one water soluble swellable anionic mucoadhesive polymer and at least one anionic pH-sensitive film-forming polymer, and further exclude non-anionic polymers.

No combination of Slavtcheff, Suzuki, or Mantelle teaches each and every limitation of the present independent claims. Likewise, no teaching of the references, express or inherent, articulates a reason leading the skilled artisan to combine the references to achieve the presently claimed combination. Still further, because of the wide range of compositions branded under the names Noveon® and Eudragit® as set forth in Mantelle and the wide range of properties thereof, the requisite reasonable expectation of success is lacking. The amended independent claims are believed to be in condition for allowance under the propositions set forth by *In re Ochiai* and *KSR Int'l*. The dependent claims are likewise believed to be allowable without consideration of

obviousness under the proposition set forth in *In re Fritch* and *In re Fine*. Reconsideration of the rejection, and allowance of the claims, is respectfully requested.

**D. THE REJECTION OF CLAIMS 33-34, 36-46, 56-57, AND 63-67 UNDER 35 U.S.C. §103(A) OVER MANTELLE IN VIEW OF SUZUKI.**

Again, for the reasons set forth above in paragraph C in rebutting the rejection over Slavtcheff/Suzuki/Mantelle, it is believed that no combination of Mantelle/Suzuki articulates any reason for the skilled artisan to contemplate the presently claimed combinations of a pH-sensitive mucoadhesive layer comprising a water-insoluble swellable anionic mucoadhesive polymer of polyacrylic acid cross-linked with polyalkenyl ether or divinyl glycol and an anionic pH-sensitive film-forming copolymer of methacrylic acid and acrylic or methacrylic ester. Reconsideration is respectfully requested.

Again, the lengthy teaching of ingredients set forth in Mantelle combined with the backing taught by Suzuki does not, without more, provide a basis for an obviousness rejection despite any recent revisions to the Manual of Patent Examining Procedure. Rather, some articulated reason for combining those teachings with a reasonable expectation of success of arriving at the presently claimed subject matter is needed, independent of the mere recitation of ingredients in the prior art and the blueprint provided by the present Applicant's specification. The trade names Noveon® and Eudragit® are applied to a range of different polymers having a range of properties, and thus Mantelle's (and the Examiner's) mere recitation of the trade names does not and cannot rise to the level of a teaching or articulated reason sufficient to provide the skilled artisan motivation to consider combining the teachings of Mantelle and Suzuki to arrive at a pH-sensitive mucoadhesive layer as recited in the present amended independent claims. As stated by the Examiner, trade names/trademarks "cannot be used properly to identify any particular material or product," given the wide range of compositions branded under the names Noveon® and Eudragit® and the wide range of properties provided by those compositions. The required articulated reason for selecting particular combinations of compositions to arrive at the claimed pH-sensitive mucoadhesive layer comprising a water-insoluble swellable anionic mucoadhesive polymer and an anionic

pH-sensitive film-forming polymer as presently claimed is lacking, and the rejection should be withdrawn. Reconsideration is respectfully requested.

#### E. CONCLUSION

All pending issues and all rejections of record are believed to have been overcome. Therefore, issuance of a prompt Notice of Allowance for the pending claims of the present application is believed to be merited and is respectfully requested. Also, in the Office Action mailed on 02/02/2004, the Examiner required restriction to a number of species relating to the claim limitation of "at least one molecule of interest." In that Action, the Examiner stated that "a claim for 'a wax-film composite' is generic" to those species. Since it is believed that the generic claim (claim 33) to the wax film composite is now in condition for allowance, rejoinder and allowance of claims 48-50 and 53-55 depending therefrom and incorporating each of its limitations is again respectfully requested.

No fees are believed to be due with this paper. However, if any unforeseen fees are due, the Commissioner is authorized to charge fees from and credit overpayments to the undersigned representative's **Deposit Account No. 11-0978**.

Respectfully submitted,

**KING & SCHICKLI, PLLC**



Patrick M. Torre  
Registration No. 55,684

247 North Broadway  
Lexington, KY 40507  
(859) 252-0889